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Efficacy of rituximab in patients with systemic sclerosis

Submission date	Recruitment status	[_] Prospectively registered
20/10/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/10/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2008	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PGNP1/8/07

Study information

Scientific Title
Efficacy of rituximab in patients with systemic sclerosis: an open label randomised controlled study

Acronym

RTX-Scleroderma

Study objectives
Systemic sclerosis (SSc) is a chronic systemic autoimmune disease characterised by vasculopathy and progressive fibrosis. Rituximab (RTX) is a chimeric monoclonal antibody (mAb) against human CD20 that depletes peripheral B cells. It has been successfully introduced in the treatment of systemic rheumatic diseases and exhibits an acceptable safety profile. The preliminary encouraging results from the use of RTX in animal models of SSc and in humans with chronic graft-versus-host disease (GVHD) has led us to investigate more thoroughly the potential efficacy of RTX in patients with SSc in an open-label, prospective, randomised, controlled study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was aproved by the Ethics Committee of Patras University Hospital in February 2008.

Study design
Single-centre, open-label, randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Systemic sclerosis (SSc)

Interventions
The participants were randomly allocated to the following two arms (ratio 1:1):
Rituximab arm: four weekly intravenous (IV) pulses of rituximab (375 mg/m^2) x 6 (24 weeks in total) and standard treatment
Control arm: standard treatment alone

Patients were fully evaluated at baseline and 24 weeks.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Rituximab

Primary outcome(s)
1. Changes in skin histology including collagen deposition and lymphocytic infiltration
2. Changes in pulmonary function as assessed by PFT

Timepoints of assessment for primary and secondary outcomes: baseline and 24 weeks.

Key secondary outcome(s))
1. Clinical assessment of skin involvement by the Modified Rodnan Skin Score (MRSS)
2. Changes in HRCT scores
3. Changes in serum levels of soluble markers
4. Changes in overall functional impairment, assessed by the Health Assessment Questionnaire (HAQ)

Timepoints of assessment for primary and secondary outcomes: baseline and 24 weeks.

Completion date
15/06/2009

Eligibility

Key inclusion criteria
1. Both males and females
2. Detection of anti-Scl-70 autoantibodies in their sera
3. Presence of SSc-associated interstitial lung disease (ILD) as indicated by findings in either high-resolution computed tomography (HRCT) of the chest or pulmonary function tests (PFT) or both
4. Absence of any changes in medications and/or dosage of treatment administered during the last 12 months before enrolment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Aged less than 18 years

Date of first enrolment
15/03/2008

Date of final enrolment
15/06/2009

Locations

Countries of recruitment
Greece

Study participating centre
25th Martiou
Patras
Greece
26504

Sponsor information

Organisation
University Hospital of Patras (Greece)

ROR
https://ror.org/03c3d1v10

Funder(s)

Funder type
Research organisation

Funder Name
Hellenic Society for Rheumatology (Greece)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration